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EXAMINER
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ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

	Application No.	Applicant(s)
Office Action Summary	10/723,364	LEE ET AL.
	Examiner	Art Unit	
	Kai Rajan	3736	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>29 November 2007</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1 - 30</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1 - 30</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
         application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/14/2007</u>.

4)☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the amendment filed November 29, 2007.

Claim Objections

Claim 20 is objected to because of the following informalities:

Claim 20 contains a typographical error. ". . .at least two at least two . . ." is disclosed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 9, 14, 15, 20, 21, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claims 2, 3, 9, 14, 15, 20, 21, 26, and 27, the term "temporal resolution" is disclosed. This term renders the claim indefinite, since the depending claims and specification do not provide sufficient clarification of the definition of "temporal resolution." The Examiner has interpreted the prior art in a manner sufficient to reject the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 8, 9 – 11, 13, 14, 16 – 20, and 25 are rejected under 35 U.S.C. 102(b)

as being anticipated by Duffin U.S. Patent No. 6,230,059, herein after referred to as '059,

which incorporates by reference in column 2, lines 59-60, Bennett et al. U.S. Patent No.

5,331,966, herein after referred to as '966.

1. A method for storing and processing physiological mechanical data in a medical

recording device having continuous mechanical data collection and mechanical data storage of

such data in plural temporal tiers, comprising:

sampling one or more physiological signals at a selected sampling rate ('059 Column 6

lines 44 – 59);

deriving physiological parameter values from the sampled signal ('059 Column 6 lines 44

– 59);

storing the parameter values as they are determined in a temporary memory buffer for a

predetermined storage interval, wherein said temporary memory buffer comprises at least two

different programmable temporal resolution values ('059 Figure 4 item S102, '966 Column 18

lines 54 – 68, column 19 lines 1 – 26);

determining a statistical aspect of the stored parameter values upon expiration of the storage interval ('059 Figure 5 item S202); and

writing the statistical aspect to a long-term memory buffer ('059 Figure 4 items S115 and S118).

2. A method according to claim 1, further comprising:

programming a unique temporal resolution to one of the at least two different programmable temporal resolution values ('059 Figure 4 item S102, '966 Column 18 lines 54 – 68, column 19 lines 1 – 26).

9. A method according to claim 2, wherein the unique temporal resolution comprises at least a one of: a coarse resolution having a relatively low temporal resolution, a medium resolution having a higher temporal resolution than said course resolution, and a fine resolution having the highest temporal resolution compared to said coarse resolution and said medium resolution ('966 Column 17 lines 26 – 68, column 18 lines 1 – 68, column 19 lines 1 – 26).

13. A method according to claim 1, further comprising:

storing the parameter values based upon at least one of: a discrete classification of the stored parameters, the temporal resolution of the stored parameters, and the total duration of storage time for said stored parameters ('059 Figure 4 items S114, S115, S118, '966 Column 17 lines 26 – 68, column 18 lines 1 – 68, column 19 lines 1 – 26).

14. A method according to claim 9, further comprising:

allocating available memory for the stored parameters based at least in part upon a respective temporal resolution assigned to each of the stored parameters., wherein said respective temporal resolution comprise said coarse resolution, said medium resolution, said fine resolution ('966 Column 17 lines 26 – 68, column 18 lines 1 – 68, column 19 lines 1 – 26).

19. An apparatus for storing and processing physiological mechanical data in a medical recording device having continuous physiologic mechanical data collection and mechanical data storage of such data in plural temporal tiers, comprising:

means for sampling one or more mechanical physiological signals at a selected sampling rate ('059 Column 6 lines 44 – 59);

means for deriving mechanical physiological parameter values from the sampled signal ('059 Column 6 lines 44 – 59);

means for storing the mechanical physiological parameter values as they are determined in a temporary memory buffer for a predetermined storage interval, wherein said means for storing includes at least two different programmable temporal resolution values ('059 Figure 4 item S102, '966 Column 18 lines 54 – 68, column 19 lines 1 – 26);

means for determining a statistical aspect of the stored parameter values upon expiration of the storage interval ('059 Figure 5 item S202); and

means for writing the statistical aspect to a long-term memory buffer ('059 Figure 4 items S115 and S118).

20. An apparatus according to claim 19, further comprising:

means for designating a unique temporal resolution to one of the at least two at least two different programmable temporal resolution values ('059 Figure 4 item S102, '966 Column 18 lines 54 – 68, column 19 lines 1 – 26).

25. A computer readable medium for storing instructions for storing and processing physiological data in a medical recording device having continuous data collection and data storage of such data in multiple time- resolved tiers, comprising:

instructions for sampling one or more physiological signals at a selected sampling rate ('059 Column 6 lines 44 – 59, figure 4 item S100);

instructions for deriving physiological parameter values from the sampled signal ('059 Column 6 lines 44 – 59);

instructions for storing the parameter values as they are determined in a temporary memory buffer for a predetermined storage interval ('059 Figure 3 item 40, figure 4 item S102);

instructions for determining a statistical aspect of the stored parameter values upon expiration of the storage interval ('059 Figure 5 item S202); and

instructions for writing the statistical aspect to a long-term memory buffer ('059 Figure 4 items S115 and S118).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
such that the subject matter as a whole would have been obvious at the time the invention was made to a person
having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
manner in which the invention was made.

Claims 1 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Duffin U.S. Patent No. 6,230,059 which incorporates by reference Bennett et al. U.S. Patent

No. 5,331,966, herein after referred to as '966, in view of Nikolic et al. U.S. Patent No.

5,743,267, and further in view of Brown U.S. Patent No. 5,997,476.

In regards to claims 1 and 19 Duffin discloses a system for sampling, processing, and

storing ECG and EMG signals ('059 Column 6 lines 44 – 59, figure 3 item 40, figure 4 items

S100, S102, S115, S118, figure 5 item S102). Duffin fails to disclose the sampling, processing,

and storing of other physiological signals such as pressure. However, Nikolic et al. a reference in

an analogous art teaches sampling, processing, and storing pressure data (Nikolic et al. column 3

line 30 – column 4 line 32, column 10 lines 55 – 65). It would have been obvious to one of

ordinary skill in the art at the time of the invention to modify the ECG sensor system of Duffin

with the pressure monitoring system of Nikolic et al., since Brown a reference in an analogous

art states that one sensor may be interchanged with another based on the condition being

monitored (Brown column 4 line 64 – column 5 line 13).

Claims 2, 3, 4, 9, 12, 20, 21, 22, and 26 – 28 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Duffin U.S. Patent No. 6,230,059, herein after referred to as '059,

which incorporates by reference Bennett et al. U.S. Patent No. 5,331,966, herein after

referred to as '966, in view of Wateridge et al. U.S. Patent No. 5,355,891.

In regards to claim 2, Duffin discloses a system for sampling, processing, and storing

ECGand EMG signals in memory buffers with different resolution values ('059 Column 6 lines

44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102). Duffin

fails to disclose *long-term* memory buffers. However, Wateridge et al. a reference in an

analogous art teaches ECG data monitoring, processing, and storing in temporal resolution

memory buffers and long term memory (Wateridge et al. column 4 lines 8 – 46, fig 1 items 13,

14). It would have been obvious to one of ordinary skill in the art at the time of the invention to

modify the storage system of Duffin with the long – term memory buffers of Wateridge et al.,

since Wateridge et al. teaches the ability to store data over an extended period of time without

large memory and power requirements, resulting in a more portable apparatus (Wateridge et al.

column 25 – 68).

3. A method according to claim 2, wherein the temporal resolution of one long-term

memory buffer is determined by the predetermined storage interval ('059 Column 6 lines 44 –

59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102, Wateridge et al.

column 4 line 8 – column 5 line 2).

4. A method according to claim 2, wherein the at least two long-term memory buffers comprise digital memory buffers ('059 Column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102, Wateridge et al. column 4 lines 8 – 46).

9. A method according to claim 2, wherein the unique temporal resolution comprises at least a one of: a coarse resolution, a medium resolution, and a fine resolution ('059 Column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102, Wateridge et al. column 4 lines 8 – 46).

12. A method according to claim 2, wherein upon expiration of a predetermined storage interval or upon exceeding available memory storage of a given long-term storage buffer the following step is performed:

transferring a set of data comprising the statistical aspect or the stored parameter values from a relatively higher temporal resolution storage medium to a relatively lower temporal resolution storage medium ('059 Column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102, Wateridge et al. column 4 lines 8 – 46).

In regards to claim 20, Duffin discloses a system for sampling, processing, and storing ECG and EMG signals in memory buffers with different resolution values ('059 Column 6 lines 44 – 59, figure 3 item 40, figure 4 items S100, S102, S115, S118, figure 5 item S102). Duffin fails to disclose *long-term* memory buffers. However, Wateridge et al. a reference in an analogous art teaches ECG data monitoring, processing, and storing in temporal resolution

memory buffers and long term memory (Wateridge et al. column 4 lines 8 – 46, fig 1 items 13,

14). It would have been obvious to one of ordinary skill in the art at the time of the invention to

modify the storage system of Duffin with the long – term memory buffers of Wateridge et al.,

since Wateridge et al. teaches the ability to store data over an extended period of time without

large memory and power requirements, resulting in a more portable apparatus (Wateridge et al.

column 25 – 68).

   See previous office action for rejections to unamended dependent claims, as they are

rejected on substantially the same basis.

Response to Arguments

   Applicant's arguments filed November 29, 2007 have been fully considered but they are

not persuasive.

   Applicant contends that Duffin fails to disclose "at least the notion of 'at least *two*

different programmable temporal resolution values.'" The Examiner disagrees.

   Duffin incorporates by reference U.S. Patent No. 5,331,966 to Bennett. Bennett discloses

setting different frequencies for data recording to separate memory buffers (Bennett column 18

lines 54 – 68, column 19 lines 1 – 26). The applied prior art is sufficient to reject the italicized

claim limitation under 35 U.S.C. 102(b).

   Applicant contends that "*neither* Duffin *nor* Wateridge *fails* to contemplate various

temporal gradations of physiologic *mechanical* data." The Examiner disagrees.

A reading of the Applicant's argument suggests that Applicant does *not* find the applied art deficient in regard to the rejected claims. However, the Examiner has assumed that the submitted remarks contained typographical errors, and that the Applicant does find the applied art deficient. The Applicant has failed to provide a definition of "mechanical." Under the broadest reasonable interpretation of "mechanical" within the scope of the claimed invention, "mechanical" is "caused or derived from machinery (dictionary.com)." In this case, Duffin discloses recording EGM signals. EGM signals are generated from the physical contraction of the heart. Therefore, EGM signals comprise "mechanical" data. The Examiner suggests that the Applicant further specify the type of "mechanical" data described in the specification within the claim language.

The Examiner has further rejected independent claims 1 and 19 under 35 U.S.C. 103(a) to show how it would be obvious to one of ordinary skill in the art to use the data collection and storage apparatus of Duffin to record other types of physiological data.

The applied prior art is sufficient to reject independent claims 1 and 19 under 35 U.S.C. 103(a) as currently presented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. R./
Examiner, Art Unit 3736
February 13, 2008

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736